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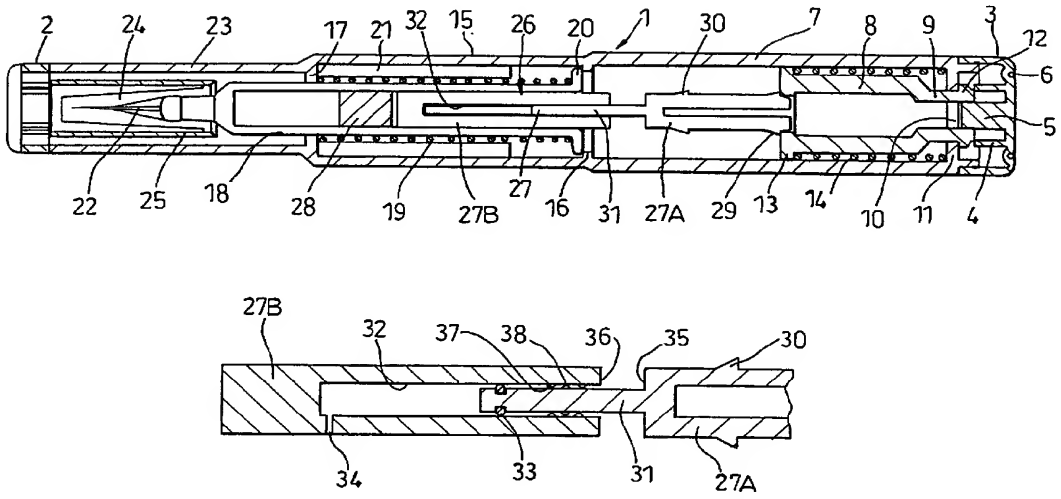
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INJECTION DEVICE WITH AUTOMATICALLY RETRACTABLE NEEDLE



(57) Abstract: An injection device has a needle which, when the device is operated, is first caused to project, then liquid is forced out through it, and finally the needle is automatically retracted. The needle extends forwardly from a capsule that can slide longitudinally within a barrel-like body, a relatively weak spring normally maintaining the capsule and needle retracted. A more powerful spring acts oppositely on a plunger formed by rod parts (27A, 27B) which, when released, shoots the capsule forward by acting on the liquid therein, and then forces the liquid out through the projecting needle. At the end of the forward stroke the plunger and capsule are decoupled and the weak spring returns the exhausted capsule and its needle to the retracted position. A lost motion connection provided by a piston (31) of the rod part (27A) acts as a damper in a cylinder (32) of the rod part (27B), to ensure that the full dose is ejected from the needle before decoupling occurs.

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INJECTION DEVICE WITH AUTOMATICALLY RETRACTABLE NEEDLE

This invention relates to injection devices, and in particular medical ones where the needle is retracted and thus made safe after use.

Such injection devices are in increasing demand for obvious reasons. There is great danger in a discarded syringe with a possibly infected needle. It is highly desirable that retraction of the needle after use should not only be possible but also be automatic. It should not rely on the user making it safe by some manipulation which can all too easily be overlooked. Also, with the increasing use of self-administered drug therapy, there is a demand for a device whereby the syringe needle is not normally visible to the user before or after the injection.

In GB-A-728248 hypodermic injection apparatus is described which meets these requirements. But the various embodiments are of considerable complexity, and therefore expense, and it is believed that none of them ever came into common use. Even though the apparatus was safe before and after injection, that is now not enough: it should preferably be cheap enough to be used once and then disposed of.

The apparatus of GB-A-728248 employs a powerful spring which, when released, thrusts forward on an ampoule and needle carrier. This projects the needle into the flesh of the patient. At the end of this phase, the spring is automatically decoupled from the carrier but continues to act on a plunger which co-operates with a piston within the ampoule. Thus the contents of the ampoule are squeezed out through the needle by the spring. At the end of this phase, the spring is automatically decoupled from the plunger, leaving the ampoule and needle carrier free to be acted upon by a relatively weak return spring, which urges the carrier back to a retracted position. There are therefore two decouplings and the complexity referred to above is largely attributable to these.

An improvement over these arrangements was developed and is described in our European Patent 0516473. However, even this arrangement can have a problem with dosage delivery. The length tolerances of the syringe, the syringe plunger and other features of the device almost invariably result in premature triggering occurring before delivery of the drug is complete. The invention aims to alleviate this problem.

According to the present invention there is provided an injection device comprising a barrel, a spring loaded drive member therein, release mechanism for allowing said member to be sprung forwardly within the barrel, a spring loaded, charged capsule within the barrel, a needle associated with the capsule initially in a retracted position at the forward end of the barrel, the spring loading of the capsule being in opposition to but weaker than the spring loading of said drive member, a plunger with which the forward end of said drive member co-operates, and a decoupling mechanism for decoupling the plunger from said drive member at the end of the forward stroke, the arrangement being such that said forward stroke first drives the capsule and the needle to a needle projecting position, said drive member acting through the plunger and the capsule charge, and secondly forces the plunger to eject the capsule charge through the needle, the capsule spring loading being then freed by the decoupling mechanism to return the capsule to the needle retracted position, the plunger including a two-part section with a delayed-motion connection therebetween whereby, in operation, the delayed-motion connection acts to delay full actuation of the plunger to the position where the decoupling mechanism is activated until such time as the plunger completes the full stroke needed to eject the required charge through the needle.

No decoupling is required at the end of the first phase; the spring loaded drive member having relatively easily projected the needle carries on more slowly

against the resistance of the capsule charge whose only escape is through the needle. The delayed-motion connection ensures that the plunger operates to eject the required full charge of liquid through the needle before the decoupling mechanism can operate to return the capsule to the needle retracted position, whereupon ejection of the charge ceases.

In the preferred arrangement the two-part section will incorporate a damper. The two-part section could be in the form of a piston and cylinder and the damper acts to delay completion of the stroke of that piston into the cylinder. The damper then can comprise an air bleed hole at the base of the cylinder, or a leaky seal of the piston contacting the internal walls of the cylinder.

The capsule will conveniently be a proprietary syringe with its plunger removed and replaced by said plunger which co-operates with said drive member.

Preferably, the spring loading will be provided by coil springs co-axial within the barrel.

The decoupling means is ideally provided by the rear end of said plunger which is abutted by said drive member and which is adapted to be deformed when it comes into co-operation with the capsule. For example, the rear end of the plunger may be bifurcated and there may be exterior projections on the fingers formed thereby, said projection when engaged by the capsule on entry therein causing the fingers to be wedged together and in this constricted condition to be free to enter a passage within the drive member.

The drive member will generally have a catch which initially is engaged with the barrel, holding the forward spring energised. The release mechanism, which may be a button-like rear end cap, frees this catch.

For a better understanding of the invention, some embodiments will now be described, by way of example, with reference to the accompanying drawings, in which:

Figures 1-4 are longitudinal sections of an injection device in progressive stages of operation; and

Figure 5 is a sectional enlarged detail of part of the plunger of the device of Figures 1 to 4.

The injection device of Figures 1 to 4 has a stepped barrel 1 reducing towards the forward end where there is a cap 2 which is removed for use. At the rear end there is a cap 3 which is snapped on by its peripheral flange and which has an inner annulus 4 and a central tab 5. The cap 3 is rotatable on the barrel 1 and its central portion can be flexed inwards, axially of the barrel, by virtue of an annular weakness 6 near the periphery.

The largest diameter portion 7 of the barrel houses a bottle shaped drive member 8 whose neck is towards the rear and which has a central aperture in its base. The neck 9 is bifurcated and extends through an aperture 10 defined by an inwardly extending flange 11. Beyond that flange the drive member 8 terminates in out-turned hooks with bevelled surfaces 12 with which the annulus 4 co-operates. At the other, forward end of the drive member 8, there is an outward flange 13, and a coil spring 14 surrounding the member acts between this and the flange 11. As shown in Figure 1, with the drive member 8 captive to the rear of the barrel, this spring is at its maximum compression.

The transition between the rear portion 7 and the intermediate portion 15 of the barrel 1 is internally defined by an annular rib 16. At the forward end of this portion 15 there is another annular rib 17 and initially a charged capsule 18 is located by these ribs, a surrounding coil spring 19 reacting against the rib 17 and urging a flange 20 at the rear of the capsule against the rib 16. The spring 19 is somewhat weaker than the spring 14 and the forward travel of the capsule, when this spring 19 becomes compressed, is limited by spacers 21 extending rearwardly from the rib 17 to provide an abutment for the flange 20.

The leading portion of the capsule 18, with a needle 22, is located in the forward end portion 23 of the barrel, the tip of the needle being set back from the end. Initially, the needle 22 is sheathed in a self-sealing silicon rubber shroud 24, protecting against contamination and leakage. The shroud is captive within an inward tubular extension 25 of the cap 2 and so is pulled off when that cap is removed just prior to use.

A plunger 26 is formed by a two-part rod 27A, 27B and a piston 28 within the capsule 18. They are not connected: the piston is provided with the capsule 18, which may be filled with its charge and plugged by the piston quite separately from the assembly of the syringe. The rear end of the rod 27 is bifurcated and near the extreme end the resultant fingers are enlarged to form exterior shouldered abutments 29 against which the annular base of the drive member 8 acts. Near the root of the bifurcation there are further enlargements 30 on opposite sides with sloping surfaces which will wedge into the rear end of the capsule 18, as described below, to close the tips of the fingers together. The two parts 27A and 27B of the rod are interconnected by a piston 31 within a cylinder 32.

For use, the cap 2 is removed taking with it the shroud 24, and the cap 3 is turned through 90° from the "safe" position in Figure 1, where the tab 5 is holding the hooks 12 apart and firmly engaged with the flange 11. The cap 3 is shown in the "use" position in Figures 2, 3 and 4. The device is then applied to where the injection is to be made and the centre of the cap 3 is pressed. The annulus 4 wedges the hooks 12 together and frees them from the flange 11. The spring 14 is then free to act and it shoots the drive member 8 forwards. The fluid in the capsule is virtually incompressible and it has a very narrow means of escape through the needle 22. The plunger 26 is therefore acting on a substantially solid body and it carries the capsule 18 forwards, compressing the spring 19. This

action terminates as shown in Figure 2, with the needle 18 projecting and the flange 20 hard up against the spacers 21.

With the capsule 18 arrested, the plunger 26 carries on under the influence of the dominant spring 14, forcing liquid out through the needle 22. As it reaches the end of the forward stroke (Figure 3) the wedges 30 act to squeeze the bifurcated end of the rod part 27A together, thus bringing the abutments 29 within the compass of the aperture at the base of the drive member 8. At this point, the drive member 8 is arrested by the rib 16, and so the spring 19 can then act, carrying the capsule 18 back with the rod end 27A passing into the drive member 8 until the flange 20 abuts the forward side of the rib 16 (Figure 4). This is the initial position of the capsule, and the needle is safe within the barrel. However, the geometry and length tolerances of the parts of the device may be such that the plunger rod 26 reaches the position where the abutments 29 enter the drive member 8 before the full required charge has been ejected from the capsule 18. In order to prevent this, the arrangement of the piston 31 within the cylinder 32 is such as to create a delayed-motion connection, whereby the full stroke of the plunger 26 to cause the wedges 30 to enter the capsule 18 is delayed until the rod part 27B has travelled sufficiently far to eject the required amount of charge from the capsule 18. The delayed-motion connection between the two parts 27A and 27B of the rod is shown in detail in Figure 5. It will be seen that the piston 31 incorporates a ring seal 33. One means of achieving a delayed-motion action of the movement of the piston 30 into the cylinder 32 would be to create the seal 33 as a "leaky" seal. Additionally or alternatively a controlled air bleed hole 34 can be provided at the base of the cylinder 32. The delayed-motion connection will be arranged to operate until such time as the rod part 27B has fully evacuated the syringe. The rod part 27A will then continue to be driven into the capsule 18 until it abuts the top of the rod part 27B, so that the wedges 30 will interact with the

capsule 18 to enable the abutments 29 to be released from the drive member 8 (as in Figure 3 of the drawings).

In order to resist the possibility that the rod part 27B might creep into rod part 27A (during storage, especially with the needle end uppermost), there could be a light clip-fit as between the ribs 37, 38. These ribs would be overridden easily by the spring 14 when the device is operated.

Drugs are currently available pre-packaged in cartridges, similar to conventional syringes but with no end flanges. Such a cartridge has a cap with a pierceable rubber membrane at the reduced diameter delivery end which accepts a double-ended needle. This is packaged inside a shield which enables it to be fitted safely and easily, as well as giving it temporary protection. To provide a flange that would make it usable with the device described above, the cartridge may be fitted inside a sleeve-like carrier. This would be similarly contoured, with a neck surrounding the delivery end of the cartridge and an outwardly projecting flange performing the function of the flange 20 at the opposite end. The neck could be threaded to retain the needle.

CLAIMS

1. An injection device comprising a barrel, a spring loaded drive member therein, release mechanism for allowing said member to be sprung forwardly within the barrel, a spring loaded, charged capsule within the barrel, a needle associated with the capsule initially in a retracted position at the forward end of the barrel, the spring loading of the capsule being in opposition to but weaker than the spring loading of said drive member, a plunger with which the forward end of said drive member co-operates, and a decoupling mechanism for decoupling the plunger from said drive member at the end of the forward stroke, the arrangement being such that said forward stroke first drives the capsule and the needle to a needle projecting position, said drive member acting through the plunger and the capsule charge, and secondly forces the plunger to eject the capsule charge through the needle, the capsule spring loading being then freed by the decoupling mechanism to return the capsule to the needle retracted position, the plunger including a two-part section with a delayed-motion connection therebetween whereby, in operation, the delayed-motion connection acts to delay full actuation of the plunger to the position where the decoupling mechanism is activated until such time as the plunger completes the full stroke needed to eject the required charge through the needle.

2. A device as claimed in claim 1, wherein said two-part section incorporates a damper.

3. A device as claimed in claim 2, wherein the two-part section is in the form of a piston and cylinder and the damper acts to delay completion of the stroke of that piston into the cylinder.

4. A device as claimed in claim 3, wherein the damper comprises an air bleed hole at the base of the cylinder.

5. A device according to claim 3, wherein the damper comprises a leaky seal of the piston contacting the internal walls of the cylinder.

6. A device as claimed in any one of claims 1 to 5, wherein the capsule is a proprietary syringe with its plunger removed and replaced by said plunger which co-operates with said drive member.

7. A device as claimed in any one of claims 1 to 6, wherein the spring loading is provided by coil springs co-axial within the barrel.

8. A device as claimed in any one of claims 1 to 7, wherein the decoupling mechanism is provided by the rear end of said plunger which is abutted by said drive member and which is adapted to be deformed when it comes into co-operation with the capsule.

9. A device as claimed in Claim 8, wherein said rear end of the plunger is bifurcated and there are exterior projections on the fingers formed thereby, said projections, when engaged by the capsule on entry therein, causing the fingers to be wedged together and in the constricted condition to be free to enter a passage within the drive member.

10. An injection device substantially as herein described, with reference to the accompanying drawings.

11. Any novel combination of features of an injection device as described herein and/or as illustrated in the accompanying drawings.

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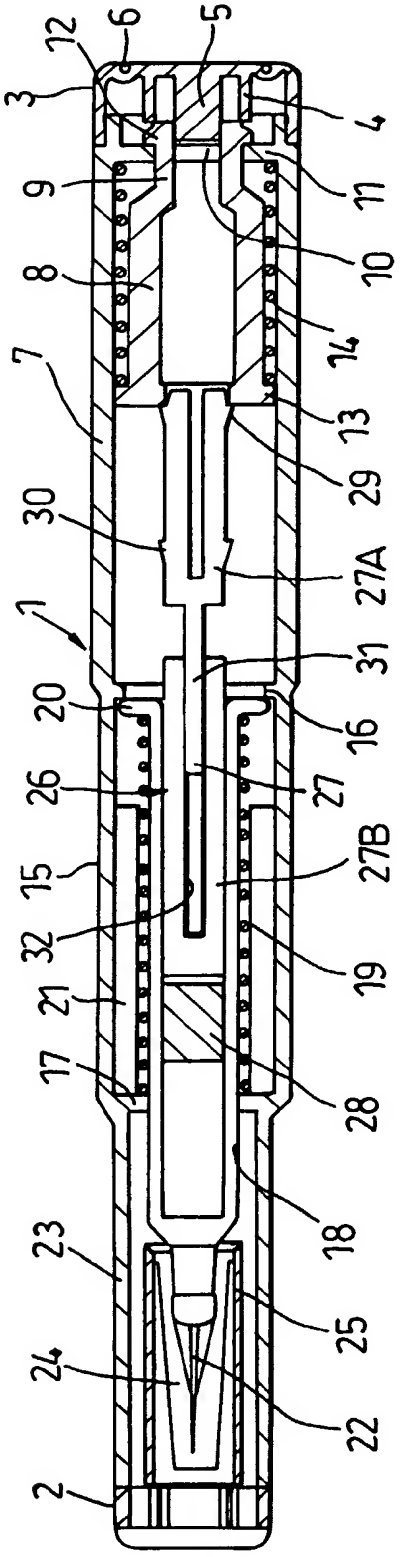
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Fig. 1

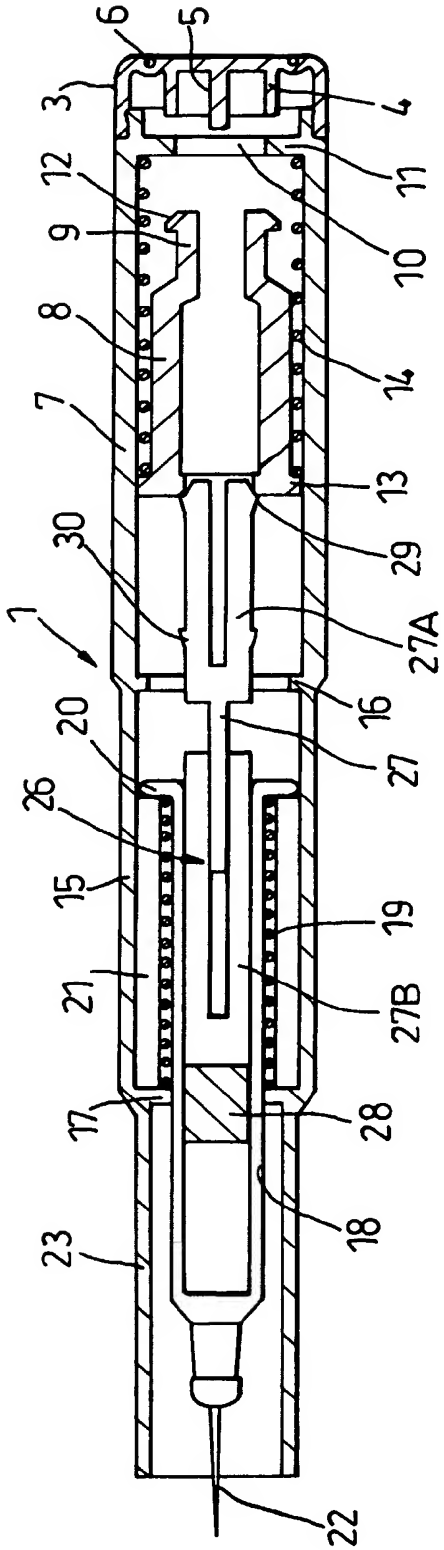
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Fig. 2

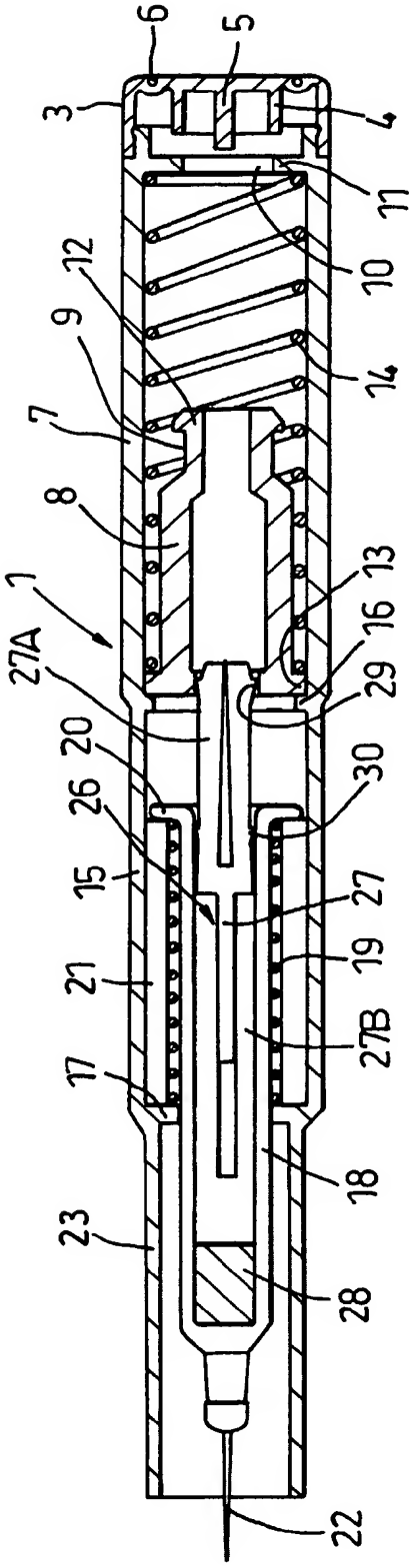
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Fig. 3

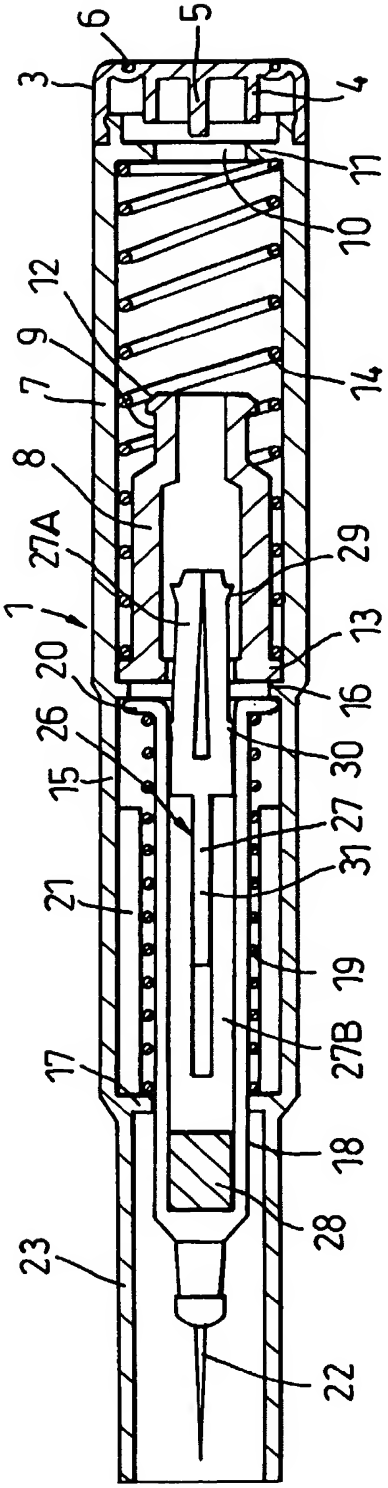
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Fig. 4

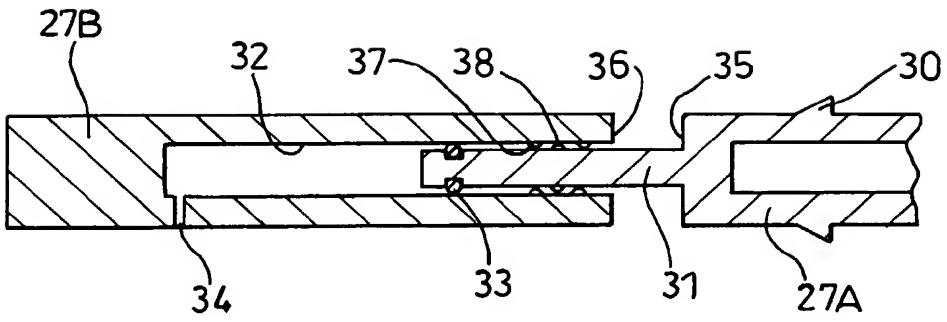

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 03/02132

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32 A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 516 473 A (OWEN MUMFORD LTD) 2 December 1992 (1992-12-02) the whole document	1-9
A	EP 0 666 084 A (BECTON DICKINSON CO) 9 August 1995 (1995-08-09) abstract; figures 3-8	1-9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2003	05/09/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ceccarelli, D

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 03/02132

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 10-11
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 10-11

The vague references to the description and the drawings render subject-matter of the claims totally obscure (Article 6 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati[redacted] Application No
PCT/GB 03/02132

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